



00115-07

PATENT

APPLICANT: M. Pamela Griffin, et al. }
ART UNIT: 3762
SERIAL NO. 09/770,653 }
EXAMINER: Frances P. Oropeza
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CUSTOMER NO.: 34444
TITLE: Method and Apparatus for the Early Diagnosis of Subacute, Potentially
Catastrophic Illness

AFFIDAVIT UNDER 37 CFR § 1.132

Commissioner for Patents
PO Box 1450, Alexandria,
VA 22313-1450

Sir:

I, Joseph Randall Moorman, declare and state as follows.

1. I am Professor of Internal Medicine at the University of Virginia.
2. I have an M.D. degree from the University of Mississippi in 1978.
3. A listing of my education, publications, projects, awards, and work history are provided in my Curriculum Vitae in the attached Appendix.
4. I am familiar with the prosecution of the above-identified Application.
5. In response to the pending rejections of the claims in this case under 35 U.S.C. § 102(b) as being anticipated by Gordon et al U.S. Patent No. 4,862,361 (hereinafter "Gordon") and 35 U.S.C. § 103 over Gordon in view Schroepfel et al U.S. Patent No. 6,035,233 (herein after "Schroepfel"), I submit the following data:

6. Gordon and/or Schroepfel fails to teach or suggest the following of the present invention:

i) A method for early detection of subacute, potentially catastrophic illness in an infant, as recited in base claim 39, which calls for:

- (a) monitoring frequency histograms of RR intervals in the infant;
- (b) identifying at least one characteristic abnormal pattern or distribution; and
- (c) correlating the at least one abnormal pattern or distribution with said illness.

ii) An apparatus for early detection of subacute, potentially catastrophic infectious illness in a patient, wherein the patient is an infant, a newborn infant, a toddler, or a child, the apparatus, as recited in base claim 69, which calls for:

- (a) a monitoring device, continuously monitoring frequency histograms of RR intervals in the patient; and
- (b) a microprocessor, identifying at least one characteristic abnormal pattern or distribution in the RR intervals that is associated with the illness.

7.

a. INTRODUCTION

For purpose of introduction of the prior art, Gordon U.S. Patent No. 4,862,361 (hereinafter "Gordon") teaches real-time monitoring of power spectra of heart rate time series. Whereas the present invention describes *inter alia* real-time monitoring of other kinds of mathematical analyses of heart rate time series. Unlike Gordon, the present invention analyses do not calculate modified or unmodified power spectra or any other frequency-domain parameter, and therefore uses entirely different mathematics and approach.

b. RECONSIDERATION

i. In particular, the Office Action (par. 2, page 3) states that Gordon discloses:

...a tachometer waveform and by using the respiratory peak within a peak and judging the value against a value of two standard deviations from the mean.

The Applicants' present invention neither calculates a tachometer waveform, nor does it

calculate a respiratory peak to be judged against two standard deviations above the mean.

- ii. In particular, the Office Action (par. 2, page 3) states that Gordon discloses:
... the R-R intervals are measured, collecting 1024 points (a ten to the third order data set), and third moment and higher data set is created

The Applicants' submit that Gordon invention does not calculate third or higher moments of the heart rate data, as described in the present invention. The Gordon invention mentions calculations of the variance, or second moment, of the RR intervals (c16). This is exclusively in the context of correcting artifacts in the data, and not for interpretation of the clinical status of the patient as in the present invention.

- iii. The Applicants' submit that the methods taught by Gordon are different than the Applicants' claimed invention. Gordon teaches a frequency domain analysis of a tachometer waveform. The Applicant's claimed invention provides a mathematical analysis based on frequency histograms of the RR intervals.

8. Moreover, the Examiner's reliance on Schroepel does not supply the deficiencies of the Gordon disclosure.

9. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements and the like so made punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code that such willful false statements may jeopardize the validity of the application of any patent issued thereon.

Date: March 12, 2004


Joseph Randall Moorman, M.D.